UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,573	07/17/2006	James B. Lorens	021044-004110US	4166

20350 7590 09/07/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,573	LORENS ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-24 and 38* is/are pending in the application.

4a) Of the above claim(s) *18 and 25-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-24 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 06/2/07 has been acknowledged.

Claims 1-17, 19-24 and 38 are examined in this office action

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Election/Restrictions

This application contains claim 18 and 25-37 are drawn to an invention nonelected with traverse in the reply filed on 12/04/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 1-17, 19-24 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Argument (written description)

The applicant argues that the scope of instant claims has been amended to SUSP-1 polypetiede having 95% identity to SEQ ID NO: 457, wherein the SUSP-1 polypeptide regulates angiogenesis in an endothelial cell for the identification of compounds that moudlates angiogensis. The applicant argues that invention as claimed

meets the written description requirements as the specficaiton teaches ffunctional assays to identify SUSP-1 polypeptides, as recited in the claims, were known to those of skill and are disclosed in the specification. The applicant argues that the assays for regulation of angiogenesis by SUSP-1 assays are disclosed in the specification at page 69, lines 19-32. SUSP-1 protein was known to have protease activity at the time of filing. See, e.g., Kim et al. J. Biol. Chem. 275:14102-14106 (2000), submitted as Exhibit A. The applicant furhter argues that example 14 of the synopsis of application of Written Description Guidelines which analyzes a claim directed to a protein having an amino acid sequence at least 95% identical to a SEQ ID NO and that has a specific activity. In these Guidelines, the Patent Office concluded that the claim was adequately described within the meaning of 35 U.S.C. §112, first paragraph. The applicant argues that the SUSP-1 protein does have protease activity as discussed in the specification.

However the applicant's arguments are found not persuasive because the scope of SUSP-1 variant (95% identity to SEQ ID NO:457) as claimed is not limited to any specific activity of the SUSP-1 but broadly encompasses the modulation of angiogenesis via any and all means. As stated earlier the disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000).

Claiming all divergent species that achieve a result as contemplated by the application without defining the representative number of species by structure and function is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. "The written description requirement has several policy objectives. The essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1566, 43USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S.

1089 (1998)." Since the specification fails to disclose a representative number of SUSP-1 species defined by structure and function, it is not possible to envision the claimed composition. One cannot describe what one has not conceived. (See Fiddes v. Baird, 30 USP2d 1481 at 1483). Therefore, the lack of disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in possessions of the huge genera recited in the claims at the time the application was filed.

Furthermore the possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Pfaff v. WellsElectronics, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).* In the instant case the SUSP-1 like polypeptide has been defined only by a statement of function that broadly encompasses a polypeptide that modulates angiogenesis, which conveyed no distinguishing information about the identity of the claimed genetic material, such as its relevant structural or physical characteristics. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of even a single member of this genus would not be representative of other nucleic acid constructs genus and is insufficient to support the claim.

Claims 1-17, 19-24 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound that modulates the expression of $\alpha V\beta 3$ integrin by modulating the biological activity of SUSP-1 (SEQ ID NO:457) in endothelial cells, does not reasonably provide enablement for a method capable of identifying compounds that modulates angiogenesis. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Argument (enablement)

The applicant argues that in view of guidance provided in the specification (Page 69, lines 29-32) and as disclosed in Kim et al. J. Biol. Chem. 275:14102-14106 (2000), it would not require and undue amount of experimentation to practice the invention as claimed.

However the applicant's arguments are found not persuasive. At best the specification teaches that the cell expressing GFP-SUSP-1 fusion protein exhibit lower level of $\alpha V\beta 3$ expression as compared to control cells (spec. page 69, example-3). The specification as filed fails to establish that the SUSP-1 is capable of modulating the angiogenesis via modulating the proliferation of *endothelial cells. Similarly, the* Kim et al. J. Biol. Chem. 275:14102-14106 (2000) *fails to disclose that SUSP-1 is capable of regulating the angiogenesis via any and all means. At best Kim et al* suggest that SUSP1 may play a role in the regulation of SUMO-1-mediated cellular processes particularly related to reproduction. In addition the specification fails to disclose a representative number of SUSP-1 species defined by both structure and function (supra). The earlier office action provides clear evidence that the regulation of angiogenesis is complex and involves cascade of cellular and transcriptional events Neither specification nor art at the time of filing teach that SUSP-1 is capable of modulating the angiogenesis. Therefore, considering the role of various cellular and transcriptional factors in the regulation of angiogenesis and limited amount of guidance provided in the specification as filed regarding the role of SUSP-1 in the modulation of angiogenesis, it is unclear how one skilled in the art would practice the invention as claimed without further extensive and undue amount of experimentation. The specification as filed fails to provide any nexus between the SUSP-1 and endothelial cells especially in context of the regulation of angiogenesis.

Furthermore regarding the variant of SUSP-1 (as clamed) it is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are

substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The applicant fails to disclose that the SUSP-1 or any varint thereof (as claimed) is capable of modulating any and all protease activities, $\alpha V\beta 3$ expression, hapatotaxis and chemotaxis, that inturn modulates the growth and proliferation of endothelial cells in order to further modulate the process of angiogenesis.

The disclosure "shall inform how to use, not how to find out how to use for themselves." See In re Gardner 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). The USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise. Thus it would requires an undue amount of experimentation to establish that a compound that merely interacts with the polypeptide or any variant thereof encoded by the amino acid sequence of SEQ ID NO:457 would modulate angiogenesis as claimed.

It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. In instant case the examples provided in the instant specification are prophetic and read as instructions rather than examples, leaving significant amount of experimentation necessary to practice the invention.

In instant case regulation of angiogenesis by modulating the expression of SUSP-1(SEQ ID NO:457) or any variant thereof (as claimed) is not considered routine

in the art and without sufficient guidance to the role of SEQ ID NO:457 or any variant thereof (as claimed) in the modulation of angiogenesis, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore considering the state of the art and limited amount of guidance provided in the instant specification, one skill in the art would have to engage in excessive and undue amount of experimentation to practice the invention as claimed.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUMESH KAUSHAL
PRIMARY EXAMINER